

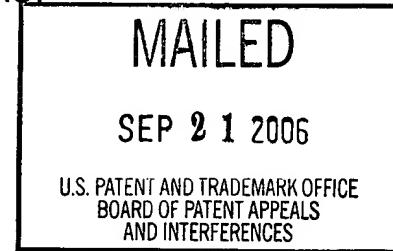
The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MAKOTO OZEKI, HARUO YAO,
TSUTOMU OKUBO and
LEKH RAJ JUNEJA

Appeal No. 2006-0108
Application No. 09/980,620



ON BRIEF

Before ADAMS, MILLS, and GREEN Administrative Patent Judges.

Opinion by MILLS, Administrative Patent Judge.

Dissenting opinion by GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-14 and 16-28, which are all the pending in this application. Claim 15 has been cancelled. Claims 1, 4, 10 and 12 read as follow:

1. A sleep-promoting composition comprising theanine.
4. A method for promoting sleep in an individual having sleep disorders, comprising administering an effective sleep promoting amount of theanine to the individual having sleep disorders.
10. The composition of claim 1, wherein the theanine is administered in an amount of from 50 to 100% by weight.

Appeal No. 2006-0108
Application No. 09/980,620

12. The composition of claim 1, wherein the composition further comprises a mineral.

The prior art references cited by the examiner are:

Katuda et al. (Katuda)	5,501,866	Mar. 26, 1996
Ekanayake	H1628	Jan. 7, 1997

Reference cited by the Merits Panel:

Ueda et al. (Ueda)	Patent Pub. US 2001/0001307 A1	May 17, 2001
--------------------	--------------------------------	--------------

Grounds of Rejection

Claims 1-4 stand rejected under 35 U.S.C. §102(b), for anticipation over Kakuda.

Claims 5-14 and 16-28 stand rejected under 35 U.S.C. §103(a), as obvious over Kakuda in view of Ekanayake.

We affirm the rejection of claims 1-3 under 35 U.S.C. §102(b) for anticipation over Kakuda. We reverse the anticipation rejection of claim 4. We affirm the obviousness rejection of composition claims 10, 12-14 and 19 over Kakuda in view of Ekanayake. We reverse the rejection of claims 5-9, 11, 16-18 and 20-28 under 35 U.S.C. §103(a), as obvious over Kakuda in view of Ekanayake.

DISCUSSION

35 U.S.C. §102(b)

Claims 1-4 stand rejected under 35 U.S.C. §102(b), for anticipation over Kakuda. Appellant has argued claims 1-3 as a group, and 4 separately. Brief, page 4. Therefore, we select claims 1 and 4 as representative claims. 37 C.F.R. §

Appeal No. 2006-0108
Application No. 09/980,620

41.37(c)(1)(vii) (September 13, 2004).

According to the examiner (Answer, page 4) Kakuda

disclose a caffeine stimulation inhibitor and a method for inhibiting caffeine stimulation comprising theanine extracted from tea leaves and/or a substance having theanine as its main active ingredient ... The composition is taught to be particularly useful for people who are hypersensitive to caffeine and/or desire to suppress the action of caffeine (including those who desire to drink tea and coffee without impairing sleep) to allow them to consume caffeine-containing beverages or foods without worry over its effects (col. 2, lines 1-62). Kakuda [] disclose that the theanine may be crude or refined theanine and the theanine content in the caffeine stimulation inhibitor is preferably 10 to no more than 500 times the amount of caffeine ingested (col. 2, lines 47-51). The caffeine stimulation inhibitor is preferably used as an additive of beverages and foods and may also be absorbed in the form of tablets, capsules, granules or syrup (col. 2, lines 63-67). Kakuda discloses a method for inhibiting caffeine stimulation wherein the caffeine stimulation inhibitor is also in powder and liquid form (claims 2 and 4).

We agree that the examiner has provided evidence to support a prima facie case of anticipation of claims 1-3. We begin, as did the examiner (Answer, page 7), with claim interpretation. "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim. . . . If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298,

Appeal No. 2006-0108
Application No. 09/980,620

1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Thus a claim preamble does not further limit claims if it merely states a purpose or intended use of subject matter. See Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481(CCPA 1951).

In the present case, we do not find that the claim preamble, "sleep promoting" offers a distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the theanine composition. Thus, with respect to the composition claims, we do not find that the claim preamble "sleep promoting," further limits the claims. In view of this claim interpretation, appellants claim 1 claims a composition comprising theanine. Kakuda describes a composition comprising theanine (abstract). We affirm the examiner's rejection as Kakuda anticipates claim 1. Claims 2 and 3 fall with claim 1.

Claim 4, a method claim, stands on a different footing than the composition claims. Claim 4 describes a method wherein the theanine is administered to an individual having sleep disorders. The examiner has not indicated, and we do not find, where Kakuda describes administration of theanine to an individual having a sleep disorder.

We acknowledge the examiner's indication (Answer, page 7) that Kakuda describes that the disclosed theanine containing composition "does not impair sleep," but we fail to see how such a statement provides for the administration of theanine to an individual having a sleep disorder. Thus, we agree with appellants, that with respect to method claim 4, the examiner has not provided evidence to support a prima facie

case of anticipation. The rejection of claim 4 for anticipation over Kakuda is reversed.

35 U.S.C. §103(a)

Claims 5-14 and 16-28 stand rejected under 35 U.S.C. §103(a), as obvious over Kakuda in view of Ekanayake. Appellants separately argue composition claim 10, and argue claims 12-14 and 19 as a single group. Brief, page 4. We select claims 10 and 12 as representative.

According to the examiner (Answer, page 5)

Kakuda [] as discussed above, teach a caffeine stimulation inhibitor... The caffeine stimulation inhibitor is preferably used as an additive of beverages and foods and may also be absorbed in the form of tablets, capsules, granules or syrup (col. 2, lines 63-67). Kakuda [] disclose various experiments and studies demonstrating the antagonistic action of theanine (col. 3-5).

Kakuda [] is deficient only in the sense that he does not teach sugars, minerals and acids in the caffeine stimulation inhibiting tea composition.

Claim 10 is directed to a theanine containing composition, wherein the theanine is administered in an amount of from 50 to 100% by weight. According to the specification page 5, "the preferred content of the theanine in the composition is for 5 to 100% by weight." Therefore, it would appear that the amount of theanine in claim 10 refers to the amount of theanine in the composition and does not relate to an amount to be administered according to body weight. The examiner argues that, "[a]though the specific range of theanine is not explicitly expressed in the art, it is the position of the examiner that it is ... obvious to one of ordinary skill in the art that suitable percentages

Appeal No. 2006-0108
Application No. 09/980,620

or amounts could be determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters." Answer, pages 13-14.

The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art," In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). Kakuda establishes that the amount of theanine in a composition is a result effective variable to those of ordinary skill in the art. For example, Kakuda discloses that the theanine content in the caffeine stimulation inhibitor is preferably 10 to no more than 500 time the amount of caffeine ingested, and thus the amount of theanine may be varied and is a result effect variable tied to countering the effects of caffeine. Kakuda, column 4, line 31, also describes a test substance, E, containing 50 mg/kg of theanine and no other substance, thus the test substance E composition is 100% theanine. Kakuda alone would appear to disclose a composition comprising 100% theanine, and claim 10 is anticipated by Kakuda. Anticipation being the epitome of obviousness, we affirm the rejection of claims 10 under 35 U.S.C. § 103 as being obvious over Kakuda in view of Ekanayake. See In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982).

With respect to claim 12, the examiner relies on Ekanayake for the disclosure of a tea extract comprising theanine which may also comprise an alkali or alkaline earth metal salt of citric acid. Column 5, lines 40-45. Answer, page 6.

Appellant argues that Kakuda [] fails to disclose a mineral and Ekanayake []

fails to disclose sleep promotion. Brief, page 21. Appellants attempt to attack each of the references individually to rebut the non-obviousness rejection. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). Ekanayake provides motivation for adding various sugars, minerals, acids and flavorings to tea extracts comprising theanine (col. 10, Example II) to counter the harsh bitter taste such tea extracts (col. 1 lines 18-67, Answer, page 6). For the reasons discussed in detail above, we conclude that the combined teachings of the cited references would have rendered obvious the composition of claim 12. Claims 13-14 and 19 fall with claim 12.

We reverse the obviousness rejection of method claims 5-9, 11 and 16-18 and 20-28 for reasons similar to the reversal of the anticipation rejection of method claim 4. We do not find the examiner has provided evidence in the prior art or record of the administration of theanine to an individual having a sleep disorder. The dissent concludes that Kakuda teaches that by taking theanine in conjunction with caffeine, one "can fall asleep faster" than if one consumed caffeine alone (i.e., consume caffeine without impairing sleep). However, such a conclusion that "one can fall asleep faster" is not a conclusion that can be drawn on the record before us. There is no

Appeal No. 2006-0108
Application No. 09/980,620

development by the examiner of any idea that a person who is hypersensitive to caffeine is a person having a sleep disorder. Nor is there any support for the conclusion that "not impairing sleep" is the equivalent of "falling asleep faster". For example, if the theanine as described in the reference counters the effects of caffeine, it would return an individual to a normal (non-caffeine sensitive) state. It is unclear how achieving a "non-caffeine sensitive state" can be equated with an advancement of sleep or "sleep promotion."

The specification states with regard to "sleep promotion", that "[t]he exhibition of the sleep promoting action of the theanine used in the present invention is determined by evaluating changes in the brainwaves in the sleep introductory phase by polygraph." Specification, pages 3-4. The record before us does not support that the suppression of hypersensitive effects of caffeine equates to a change in brainwaves in the sleep introductory phase.

Thus, we agree with appellants, that with respect to method claims 5-9, 11 and 16-18 and 20-28, that the examiner has not established a prima facie case of obviousness.

Other Issue for Consideration

Upon return of the application to the Examiner, it is recommended that the examiner determine the relevance of Ueda et al., PCT publication WO99/42096, published August 26, 1999 (attached). The present application claims priority to an

Appeal No. 2006-0108
Application No. 09/980,620

April 5, 2000 Japanese patent application and thus the PCT publication is before the filing date of the priority document for the present application.. [See also Patent Publication US 2001/0001307 A1, dated May 17, 2001 and related issued patents 6,831,103B1 and 6,589,566B2 (attached).] The PCT publication claims priority to a Japanese patent application filed in 1995, also presumably published. It is recommended that the examiner consider the relevance of PCT publication WO99/42096 to the pending claims and also determine if there are any related, relevant Japanese patent family publications. Note the 6,821,103 patent, a presumed translation of PCT WO99/42096, column 3, paragraph 57, discloses a composition comprising theanine is useful in the amelioration of sleep disorders. See also Example 12, column 18.

CONCLUSION

We affirm the rejection of claims 1-3 under 35 U.S.C. §102(b) for anticipation over Kakuda. We reverse the anticipation rejection of claim 4. We reverse the rejection of claims 5-9, 11 and 16-18 and 20-28 under 35 U.S.C. §103(a), as obvious over Kakuda in view of Ekanayake. We affirm the rejection of claims 10, 12-14 and 19

Appeal No. 2006-0108
Application No. 09/980,620

over Kakuda in view of Ekanayake. The application is returned to the examiner for consideration of the relevance of PCT Publication WO99/42096 to the pending claims.

AFFIRMED-IN-PART



DONALD E. ADAMS
Administrative Patent Judge



DEMETRA J. MILLS
Administrative Patent Judge

) BOARD OF PATENT
)
) APPEALS AND
)
) INTERFERENCES
)

GREEN, Administrative Patent Judge, concurring-in-part; dissenting-in-part.

I agree with the majority that the examiner has made out a prima facie case of unpatentability as to claims 1-3, 10, 12-14 and 19. I would go farther, however, and also affirm the rejection under 35 U.S.C. § 102(b) as to claim 4, and the obviousness rejection as to claims 5-9, 11, 20, 21 and 25-28.

Claim 4 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Kakuda.

Claim 4 is drawn to “[a] method for promoting sleep in an individual having sleep disorders, comprising administering an effective sleep promoting amount of theanine to the individual having sleeping disorders.”

As I see it, the issue of whether Kakuda anticipates the method of claim 4 rests on the interpretation of “sleep disorders.” “[C]laims ‘must be read in view of the specification, of which they are a part,’” as “the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a . . . term.’” Phillips v. ATWH Corp., 415 F.3d 1301, 1315, 75 USPQ2d 1321, 1327 (Fed. Cir. 2005) (en banc) (citations omitted). Moreover, during ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. See In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

The instant specification states that “the term ‘promoting sleep’ in the present specification refers to promoting a natural progression of sleep with maintaining homeostasis of a living body regarding sleep.” Id. at 3. Thus, “the composition of the present invention comprising theanine can be used, for instance, to moderate or ameliorate various sleep disorders caused by changes in the body rhythm, such as insomnia, sleeplessness (difficulty in falling asleep), vigilance in middle of sleep, vigilance in early morning, and disturbance of restful sleep.” Id.

With respect to “promoting sleep,” the specification states “[t]he time periods until entering the sleeping state are compared between an individual administered with the theanine and an individual without administration. When the individual administered with the theanine enters the sleeping state earlier than the individual without administration, it is judged that the sleep promoting action of theanine is exhibited.” Id. at 4-5.

Finally, the specification teaches that the theanine may be administered as a “liquid food,” such as “green tea, oolong tea, black tea and herb tea, . . . carbonated beverages, soft drinks, . . . and the like.” Id. at 7-8.

Thus, the claim reads on a method in which theanine is administered to treat a sleep disorder, such as sleeplessness, wherein the patient falls asleep faster with the theanine than if no theanine were administered.

With respect to the rejection, as noted in the Examiner’s Answer, Kakuda teaches the use of theanine to counter effect the effects of caffeine. See Examiner’s Answer, page 4. With respect to sleep, Kakuda teaches:

By refining theanine, frequently contained in caffeine-containing beverages and foods such as tea and coffee, and using it as an active ingredient, in addition to it being able to be used as a harmless additive, by using theanine and/or compositions having theanine as their active ingredient in caffeine-containing beverages and foods, a caffeine stimulation inhibitor can be provided that allows those people who desire to suppress the action of caffeine (including, but not limited to, those people who desire to drink tea and coffee without impairing sleep) without worry over its effects.

Id. at Col. 2, lines 52-62.

Thus, Kakuda teaches that by taking theanine in conjunction with caffeine, one can fall asleep faster than if one consumed caffeine alone (*i.e.*, consume caffeine without impairing sleep). Kakuda therefore teaches a method in which sleepless, a sleep disorder as defined by the instant specification, is ameliorated by the administration of theanine, and anticipates the method of claim 4.

Appellants argue that “without impairing sleep” as used by Kakuda “means that one is able to sleep as if one did not take caffeine.” Appeal Brief, page 6. Thus, according to appellants, Kakuda does not teach “sleep promotion,” but only teaches “not impairing sleep,” *i.e.*, the ability to sleep normally. See id.

Appellants argue further that caffeine has many effects, such as nervousness, shaking, and alertness, and Kakuda teaches the use of theanine to counter those effects, as well as not impairing sleep. See id. at 6. According to appellants, “Kakuda [] does not disclose or suggest taking theanine in the absence of caffeine as is present in Examples 3 and 4 of the instant written description. Even in the absence of caffeine, theanine is useful for promoting sleep.” Id.

As discussed above, by taking theanine along with caffeine, one falls asleep faster than if one had consumed caffeine alone, and thus the reference teaches treating the sleep disorder of sleeplessness, as defined by the instant specification. Neither the specification nor the claim limits the reason that an individual may be suffering from sleeplessness, and thus the claim reads on the consumption of caffeine as the reason for the sleeplessness. Moreover, the claim does not specify that the individual is only suffering from a sleep disorder, thus it is irrelevant that the individual may have shaking and nervousness that are also ameliorated by the theanine.

With respect to the obviousness rejection of claims 5-7, 11 and 16-18, claim 5 is representative. Claim 5 is drawn to “[a] method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid.

Appellants reiterate their arguments as to why Kakuda does not teach a method of promoting sleep in an individual having a sleep disorder, and their arguments as to why the combination is improper. See Appeal Brief, page 12. Thus, I would affirm for the reasons set forth above with respect to the anticipation rejection of claim 4, and the reasons set forth by the majority as to the prima facie case of obviousness.

Appellants additionally argue that there are many causes of sleep disorders, and that ingesting caffeine is not one of them. See id. at 15. But as noted above, sleeplessness is defined as being a sleep disorder, and as recognized by Kakuda, caffeine, a known stimulant, is also known to cause

sleeplessness. There is nothing in the specification or the claims that excludes caffeine as being the cause of said sleeplessness.

With respect to the obviousness rejection of claims 8 and 9, claim 8 is representative. Claim 8 is drawn to “[t]he method according to claim 4, wherein said sleep disorders are those caused by changes in a body rhythm.”

Appellants assert that “the Examiner has implicitly acknowledged that Kakuda [] does not disclose sleep disorders caused by changes in body rhythm as appears in claim 8. Because this is the only additional element in claim 8 that does not appear in claim 4, the Examiner has acknowledged that a body rhythm disorder does not occur in Kakuda [].” Appeal Brief, pages 17-18.

I agree with appellants that if Kakuda teaches the treatment of a sleep disorder such as sleeplessness, it implicitly teaches a sleep disorder caused by a change in body rhythm. Thus, I would affirm on the basis as set forth for claim 4, as anticipation is the epitome of obviousness. See In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982).

With respect to the obviousness rejection of claims 20 and 28, claim 20 is representative. Claim 20 is drawn to “[t]he method of claim 5, wherein the composition is administered at a dose of 0.2 to 200 mg/kg weight.”

Appellants argue that Kakuda in Example 1 teaches away from that limitation. See Appeal Brief, pages 22-23. According to appellants, mice were given theanine in amounts of 174 mg/kg or 1740 mg/kg. See id. at 22. The mice given 174 mg/kg of theanine “appeared to demonstrate the exact same effects as the mice that were given no theanine but given caffeine,” whereas the mice

given 1740 mg/kg appeared to exhibit the same effects as the control mice that were given neither caffeine nor theanine. Id. Appellants conclude “that theanine is effective if the dosage is increased 10 fold to 1740 mg/kg but is ineffective at a dose of 174 mg/kg.” Id.

Appellants’ arguments are not found to be convincing. First, Kakuda specifically teaches that the amount of theanine administered is relative to the amount of caffeine administered, being preferably 10 times but no more than 500 times the amount of caffeine ingested. See id. at Col. 2, lines 48-51.

In addition, in Example 1, Kakuda teaches that the increase in spontaneous movement in the group of mice that ingested 174 mg/kg of theanine along with the caffeine was more inhibited than the group consuming caffeine alone, and that the group that ingested 174 mg/kg of theanine did not demonstrate an increasing trend, and that the amount of spontaneous movement decreased slightly in the latter half of the experiment. See id. at Col. 3, line 59-Col. 4, line 9. Moreover, Example 2 demonstrates that in rats that ingested the same dose of caffeine as the mice in Example 1 and 50 mg/kg of theanine demonstrated “the presence of caffeine stimulation inhibitory action due to the antagonistic action of caffeine on caffeine.” Id. at Col. 4, lines 60-64. Thus, when the Kakuda reference is read as a whole, it does not teach away from the dose of claim 5.

With respect to the obviousness rejection of claims 21 and 25-27, claim 21 is representative. Claim 21 is drawn to “[a] method for promoting sleep in a human having a sleep disorder, comprising: administering to a human an

effective amount of theanine to moderate or ameliorate a sleep disorder selected from the group consisting of insomnia, vigilance in middle of sleep, vigilance in early morning and disturbance of restful sleep." As sleeplessness encompasses "disturbance of restful sleep," I would affirm the rejection of this claim for the same reason I would affirm the rejection of claim 8.

Finally, I agree with the majority that the obviousness rejection of claims 22-24 should be reversed, but for different reasons than the majority.

Claim 22 is drawn to a method of promoting sleep in a human having a sleep disorder, wherein the human suffers from insomnia. In claim 23, the sleep disorder is vigilance in middle of sleep, and claim 24 is vigilance in early morning. While sleeplessness, and therefore disturbance of restful sleep, would be understood by the ordinary artisan to be a side effect of caffeine, not so insomnia or vigilance.

Thus, in my opinion, the examiner has established, by a preponderance of the evidence, that claim 4 is anticipated by Kakuda, and that claims 5-9, 11, 20, 21 and 25-28 are rendered obvious by the combination of Kakuda and Ekanayake, and I would affirm those rejections.


LORA M. GREEN
Administrative Patent Judge

) BOARD OF PATENT
)
) APPEALS AND
)
) INTERFERENCES

Appeal No. 2006-0108
Application No. 09/980,620

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
Falls Church, VA 22040-0747